PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/32

A1

(11) International Publication Number: WO 92/11885

(43) International Publication Date: 23 July 1992 (23.07.92)

(21) International Application Number: PCT/US92/00328

(22) International Filing Date: 13 January 1992 (13.01.92)

(30) Priority data:
640,709 14 January 1991 (14.01.91) US

(71) Applicant: PRECISION DYNAMICS CORPORATION [US/US]; 13880 Del Sur Street, San Fernando, CA 91340-3490 (US).

(71)(72) Applicant and Inventor: LAM, David [US/US]; 931 Percheron Drive, Walnut, CA 91789 (US).

(74) Agents: HOLLAND, J., Mark et al.; Thomas P. Mahoney Law Offices, 4000 MacArthur Boulevard, Suite 6200, Newport Beach, CA 92660 (US).

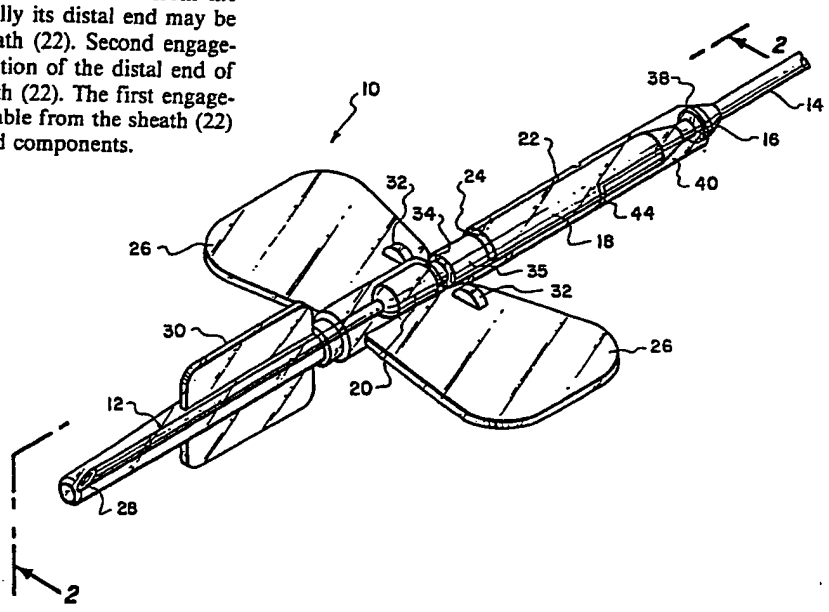
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP (Utility model), NL (European patent), NO, SE (European patent).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CANNULA GUARD

(57) Abstract

A guard for a cannula (12) is characterized by an outer tubular sheath (22) slidably disposed about the cannula. The tubular sheath (22) includes first engagement tabs (32) to engage the cannula (12) and facilitate insertion of the cannula (12) into a patient. Simultaneously with removal of the cannula from the patient, the cannula (12) and specifically its distal end may be slidably withdrawn into the outer sheath (22). Second engagement tabs (40) permit permanent retention of the distal end of the cannula (12) within the outer sheath (22). The first engagement tabs (32) are preferably demountable from the sheath (22) to facilitate ease of disposal of the used components.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland			SE	Sweden
CI	Côte d'Ivoire	KR	Republic of Korea	SN	Senegal
CM	Cameroon	LI	Liechtenstein	SU	Soviet Union
CS	Czechoslovakia	LK	Sri Lanka	TD	Chad
DE	Germany	LU	Luxembourg	TG	Togo
DK	Denmark	MC	Monaco	US	United States of America

CANNULA GUARD

Background of the invention:

This invention generally relates to safety guards for cannular devices, and specifically to a cannula guard useful in taking blood donations, performing blood transfusions, administering medication or the like. The guard of the invention is characterized by an outer sheath member slidably disposed about the cannula. The outer sheath may be operably engaged with the cannula to facilitate insertion of the cannula into a patient, and when the cannula is withdrawn from the patient, the same motion retracts the cannula (including specifically the exposed distal tip thereof) within the outer sheath and accomplishes permanent retention of the distal tip within the outer sheath.

Numerous devices have been proposed to reduce the danger of handling potentially contaminated needles, cannulas and the like. It is well known that, for example, handling and disposal of used cannular needles exposes nurses, doctors and other persons to the risk that they will be pricked by the pointed, distal end of the needle and possibly become infected with AIDS or another disease.

Among the devices presently available to address this problem are U.S. Pat. Nos. 4,778,453 and 4,782,841 to Lopez, and U.S. Pat. No. 4,820,282 to Hogan. The Lopez patents disclose guards usable with hypodermic syringes and require that the needle assemblies be screwed onto the syringe. For that reason, the Lopez guards are not readily adaptable for use in cannular applications. Moreover, the devices of the Lopez patents leave a substantial portion of the used needle exposed to subsequent handlers of the assembly, and the '841 patent even leaves the proximate end of its needle 26 in a dangerously unprotected state after removal from the syringe.

The well-known use of "butterfly needles" is illustrated in the Hogan '282 patent. The guard of Hogan has significant shortcomings, however, including the facts that the guard is separate from the "butterfly" structure rather than being packaged and utilized as a single unit, and that the manipulation of the guard during its use may cause substantial, and predictably painful or uncomfortable, movement of the cannula within the patient's body.

Our invention, in contrast, provides the simplicity of a single unitized butterfly needle and guard, and accomplishes substantially complete coverage of the used needle virtually immediately upon withdrawal of the needle from the patient.

Objects and Advantages of the Invention:

It is, therefore, an object of our invention to provide a cannular guard device which is characterized by its incorporation of traditional "butterfly needle" features and benefits while providing a relatively permanent and safe covering for the cannula after use, in order to protect against subsequent contact or contamination by the cannula.

The cannula guard of our invention preferably includes a tubular outer sleeve or sheath member slidably disposed around the cannula. After removal of a cover from the distal tip of the cannula, butterfly- or wing-shaped strips attached to or demountably associated with the sheath member are gripped in the normal manner to manipulate the cannula for insertion. The butterfly- or wing-shaped strips of our invention preferably include engagement tabs on the inner surfaces thereof to engage the cannula, thereby permitting controlled manipulation of the cannula and needle during insertion and reducing or eliminating any relative sliding movement between th sheath and the cannula.

In a typical application, after insertion of the cannula, the butterfly strips are taped to the patient's body to minimize movement of the cannula assembly with respect to the patient. When removing the cannula from the patient's body after use, the potentially contaminated distal tip may be simultaneously retracted into and retained within the sheath, minimizing any risk that subsequent handling of the assembly will cause injury or infection.

Another object of the invention is the provision of a cannular guard which may be readily utilized by personnel without the need for substantial training. As noted above, the device of our invention incorporates a similar physical structure as in presently utilized butterfly needles, and the use of our invention entails relatively minor departures from that of such needles.

An additional object of our invention is the provision of a guard of the aforementioned character which is relatively easy to manufacture, package and handle. The various components are readily fabricated through injection- or insert-molding processes or the like. Prior to disposal, the "butterfly wings" of the preferred embodiment may be removed from the remainder of the assembly to facilitate such disposal.

Moreover, because of the unitary nature of the guard assembly of our invention, personnel utilizing the device do not have to search for or assemble any components when using the device of our invention.

Yet another object of our invention is the provision of a guard of the aforementioned character which incorporates cannular means having a distal end for insertion in a patient and a proximate end operably connected to fluid receiving means and an outer sh ath member slidably disposed about said

cannular means. First engagement means is preferably provided for engaging the cannular means and the outer sheath member with one another to enable insertion of said distal end of the cannula into the patient. Second engagement means is provided for retaining said distal end of the cannular means within the outer sheath member after said distal end has been slidably retracted thereinto.

Still another object of our invention is the provision of a needle guard for covering a hollow needle after insertion and removal of said needle from a patient which includes a first tubular member having first and second ends thereof with the needle operatively affixed to said first end whereby fluid may flow from the patient through the needle, then through the first end of the first tubular member, and finally through the second end of the first tubular member. A second tubular member is slidably disposed about the first tubular member, and first engagement means engaging the second tubular member with said first tubular member facilitates the insertion of the needle. Second engagement means permanently engages the first tubular member with the second tubular member after the needle has been positioned within the second tubular member.

Other objects and advantages of the invention will be apparent from the following specification and the accompanying drawings, which are for the purpose of illustration only.

Brief Description of the Drawings:

FIG. 1 is an isometric view of a cannula guard assembly constructed in accordance with the teachings of the invention;

FIG. 2 is a partially sectional view, taken along line 2-2 of FIG. 1;

FIG. 3 is an isometric view of the cannula guard of FIG. 1, having the distal end of the cannula exposed and indicating the flexibility of wing-shaped gripping members;

FIG. 4 is a partially sectional view, taken along line 4-4 of FIG. 3;

FIG. 5 is a view similar to FIG. 4, illustrating the sliding retraction of the cannula within an outer sheath member;

FIG. 6 is a view similar to FIG. 5, illustrating the completed retraction of the cannula into the outer sheath member;

FIG. 7 is a sectional view, taken along line 7-7 of Fig. 6; and

FIG. 8 is a sectional view similar to FIG. 7, illustrating an alternative embodiment of the invention.

Description of Preferred Embodiment:

Referring to the drawings, and particularly to FIGS. 1 and 2 thereof, I show a cannula guard assembly 10 constructed in accordance with the teachings of the invention and including cannular means such as a stainless steel needle 12 operably affixed to fluid receiving means such as a flexible tube 14. Although many of the components illustrated in the drawings are shown as transparent or in phantom, those skilled in the art will understand that such representation facilitates this disclosure and is not intended as a limitation regarding the opacity of the various materials to be utilized in the invention.

In the preferred embodiment, the needle 12 is attached to the tube 14 at a neck 16. The section of the needle 12 adjacent the neck 16 is coated or otherwise molded, such as through an insert- or injection-molding process, with a plastic or other suitable annular layer 18. A preferred material for this coating is polypropylene, although any of a wide variety of materials may be utilized with efficacy. Various structural features of the outer surface of the coating 18, and the utility thereof, are discussed below.

In an alternative embodiment, the annular coating 18 may constitute a first tubular member 18, with the needle 12 operably affixed to a first end 20 of the tubular member 18, and the neck 16 constituting a second end of the tubular member 18. In such an alternative embodiment, the cannular means 12 does not extend through the length of the cannula guard assembly 10, but instead terminates in an intermediate portion thereof.

A second tubular member such as a sheath 22 is slidably disposed about the cannular means 12 and preferably in contiguous relationship with the coating 18. The sheath 22 may be fabricated from polypropylene, polyethylene or some other suitable material. The sheath includes an opening 24 along one side thereof.

The assembly further preferably includes gripping means such as butterfly-shaped or wing-shaped strips 26 operably associated with the sheath 22. In the preferred embodiment, the gripping means 26 is fabricated from polyethylene or a similar material and is demountable from the sheath, although those skilled in the art will understand that the wing-shaped strips may be permanently affixed or ven integrally molded with the sheath 22.

The wing-shaped strips 26 preferably include projections 32 positioned to be cooperatingly received in a necked-down portion 34 or similar expedient on the coating 18. As illustrated in FIG. 3, the strips 26 may be readily raised upwardly into contiguous relationship with one another, thereby engaging the projections 32 are operably disposed in the necked-down portion 34. In such a position, the assembly 10 may be readily manipulated to insert the distal end 28 of the needle 12 into a patient, by grasping the wings 26. The engagement of the projections 32 in the necked-down portion 34 precludes axial displacement of the cannular means with respect to the gripping means 26.

Also shown in FIGS. 1 and 2 is a removable cover 30 for the distal end 28 of the needle 12. The cover 30 is provided for protective purposes during transport and initial handling of the assembly, but is removed prior to use of the cannula, resulting in a structure such as that shown in FIGS. 3-6.

After insertion of the cannula into a patient, the butterfly strips may be utilized in a conventional manner to maintain the cannula assembly in a fixed position on the patient's arm, such as by juxtaposing the wings 26 with the patient's skin and placing adhesive tape across the assembly and the patient's adjacent skin.

In a preferred use of the invention, the same or additional strips of tape are placed across the opening 24 and operably adhered to a surface 35 of the coating 18 adjacent the necked-down portion 34. By this or a similar expedient, additional stability and resistance to movement is provided to the assembly while in use. Of course, prior to removing the cannula from the patient's arm (as more thoroughly described below), the tape or other expedient should then be disengaged

from the surface 35 to facilitate the sliding removal of the cannula from the sheath.

Those skilled in the art will understand that a wide variety of retention means, such as the aforedescribed combination of the opening 24, the surface 35, and operably located adhesive tape (not shown), may be effectively utilized to accomplish the desired purpose without departing from the teachings of the invention.

As best shown in FIG. 5, the aforementioned various structural features of the coating 18 include a land 36 adjacent the neck 16. The end 38 of the outer sheath 22 further includes engagement tabs 40 pivotable at detents 44 or otherwise flexible as necessary to achieve the functions described below and having engaging portions 42 disposed on the inward surfaces thereof. As originally provided, FIGS. 1-4, the engaging portions 42 abut the land 36 to prevent dislodgement of the sheath 22 over the tube 14.

After use of the cannula has been completed, the distal end 28 of the needle 12 is removed from the patient by pulling on the tube 14, as indicated in FIGS. 4-6. During such pulling manipulation, the butterfly strips 26 are preferably held in place on the patient's skin by the aforementioned tape and/or light pressure from an attendant's hand. Thus, the inner cannular needle 12 and its coating or tube member 18 is slidably displaced with respect to the outer sleeve or sheath 22.

During this sliding action and as a result thereof, the engaging portions 42 ride up the ramped surface 46 of the coating or tube 18, effectively spreading the flexible engagement tabs or fingers 40 to permit the desired sliding withdrawal of the needle within the sheath 22.

An intermediate stage of such withdrawal is illustrated in FIG. 5. As shown in FIG. 6, such sliding withdrawal eventually results in the engagement of the engaging portions 42 of the flexible engagement tabs or fingers 40 with the slot or necked-down portion 34. In this position, the distal end 28 of the needle is contained within the sheath 22 and inadvertent pricking or other contact with the end are avoided. Utilization of appropriate materials for the various components can result in effective "permanent" retention of the distal end 28 of the needle in this position.

The preferred internal configuration of the engaging portions 42 is illustrated in FIG. 7. An internal cooperating means such as illustrated in FIG. 8 may be provided on the engaging portions 42 to prevent rotation of the sheath about the lengthwise axis of the needle 12. To prevent such rotation when the assembly is in the permanent configuration, FIG. 6, projections such as projections 48 may be provided at the necked-down portion 34. Cooperating slots 50 operatively receive the projections 48 and preclude the undesirable rotation. Similar projections may also be provided, of course, adjacent the land 36 and ramped surface 46 to preclude such rotation prior to utilization of the assembly. Through simple modification, not shown, such rotation could likewise be prevented during the entire retraction of the needle 12 within the sheath 22.

Thus, by our invention, we provide a simple device to reduce the risks associated with utilization of cannular devices. The distal end 28 of the cannular needle may be "permanently" sheathed virtually immediately upon removal of the cannula from the patient's body.

The cannula guard of our invention has been described with some particularity but the specific designs and constructions

disclosed are not to be taken as delimiting of the invention in that various modifications will at once make themselves apparent to those of ordinary skill in the art, all of which will not depart from the essence of the invention and all such changes and modifications are intended to be encompassed within the appended claims.

WE CLAIM:

1. In a cannula guard assembly, the combination of: cannular means having a distal end for insertion in a patient and a proximate end operably connected to fluid receiving means; an outer sheath member slidably disposed about said cannular means; first engagement means for engaging said cannular means and said outer sheath member with one another to enable insertion of said distal end into said patient; and second engagement means for retaining said distal end of said cannular means within said outer sheath member after said distal end has been slidably retracted thereinto.

2. The assembly of Claim 1, in which said outer sheath member includes gripping means associated therewith.

3. The guard of Claim 2, in which said gripping means is demountably associated with said second tubular member.

4. The assembly of Claim 2, in which said gripping means are constituted by butterfly-shaped strips.

5. The assembly of Claim 2 or Claim 3 or Claim 4, in which said first engagement means include projecting portions operably disposed on said gripping means to be selectively engaged in corresponding receiving portions on said cannular means.

6. The assembly of Claim 1 or Claim 2 or Claim 3 or Claim 4, in which said second engagement means includes flexible engagement tabs.

7. The assembly of Claim 6, in which said flexible engagement tabs are adapted to permit said slidable retraction of said distal end into said outer sheath member and to

subsequently engage receiving means on said cannular means, whereby said retention of said distal end in said outer sheath member is achieved.

8. The assembly of Claim 1 or Claim 2 or Claim 3 or Claim 4, including retention means for retaining said cannular means in a relatively fixed position with respect to said patient, after insertion of said cannular means into said patient and prior to said retraction of said distal end into said outer sheath.

9. In a needle guard for covering a hollow needle after insertion and removal of said needle from a patient, the combination of: a first tubular member having first and second ends thereof, said needle operatively affixed to said first end whereby fluid may flow from said patient through said needle then through said first end of said first tubular member and finally through said second end of said first tubular member; a second tubular member slidably disposed about said first tubular member; first engagement means for engaging said second tubular member with said first tubular member to facilitate said insertion of said needle; and second engagement means for permanently engaging said first tubular member with said second tubular member after said first tubular member and said needle affixed thereto have been actuated to position said needle within said second tubular member.

10. The guard of Claim 9, in which said second tubular member includes gripping means associated therewith.

11. The guard of Claim 10, in which said gripping means is demountably associated with said second tubular member.

12. The assembly of Claim 10, in which said gripping means are constituted by butterfly-shaped strips.

13. The assembly of Claim 10 or Claim 11 or Claim 12, in which said first engagement means include projecting portions operably disposed on said gripping means to be selectively engaged in corresponding receiving portions on said first tubular member.

14. The assembly of Claim 9 or Claim 10 or Claim 11 or Claim 12, in which said second engagement means includes flexible engagement tabs.

15. The assembly of Claim 14, in which said flexible engagement tabs are adapted to permit said slidable retraction of said distal end into said outer sheath member and to subsequently engage receiving means on said cannular means, whereby said retention of said distal end in said outer sheath member is achieved.

16. The assembly of Claim 9 Claim 10 or Claim 11 or Claim 12, including retention means for retaining said needle in a relatively fixed position with respect to said patient, after insertion of said needle into said patient and prior to said actuation of said needle into said second tubular member.

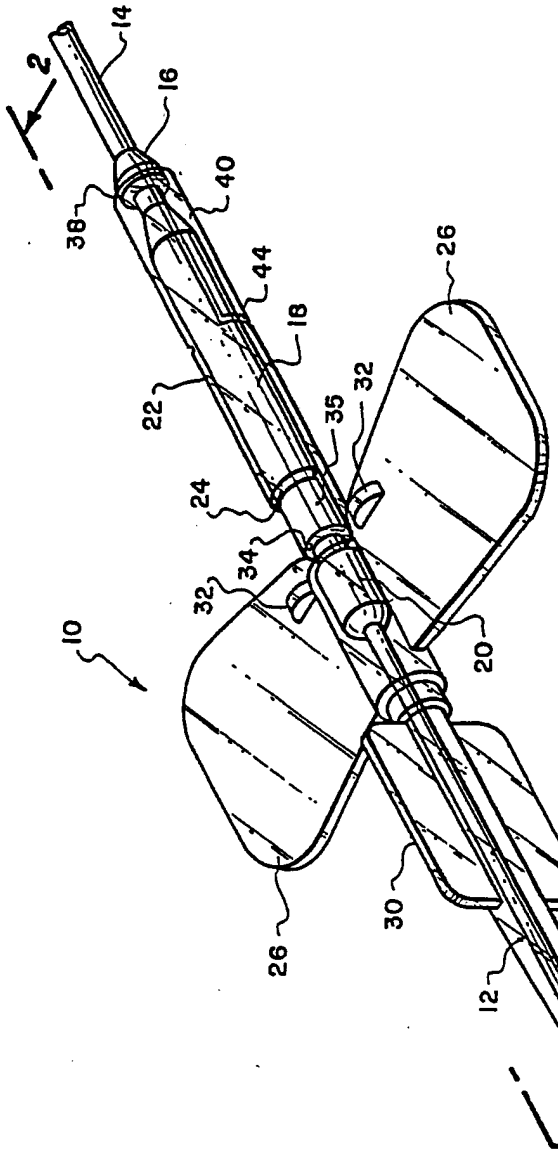

14
16
2
38
40
44
18
22
35
32
24
34
32
10
26
20
26
30
12
28
2

Fig. 1.

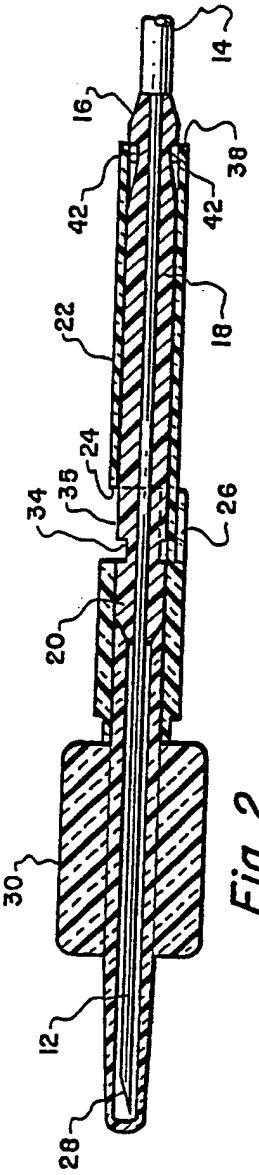

14
16
38
42
42
22
18
24
35
34
26
20
30
12
28

Fig. 2.

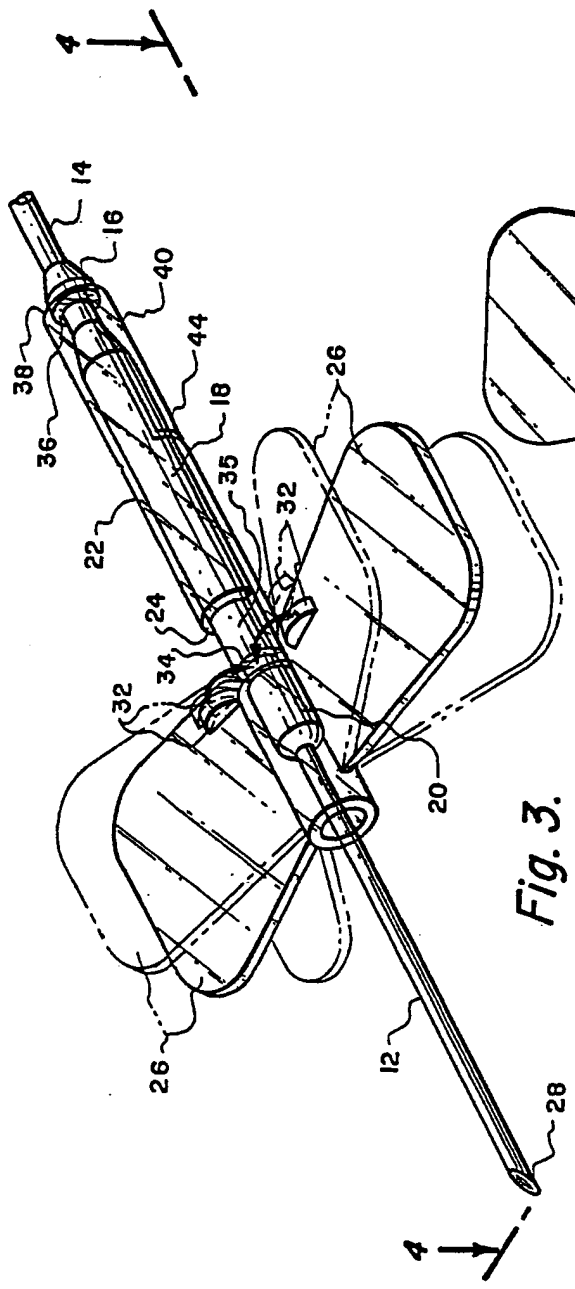

4
14
16
40
44
38
18
36
35
32
22
24
34
32
26
20
12
28
4

Fig. 3.

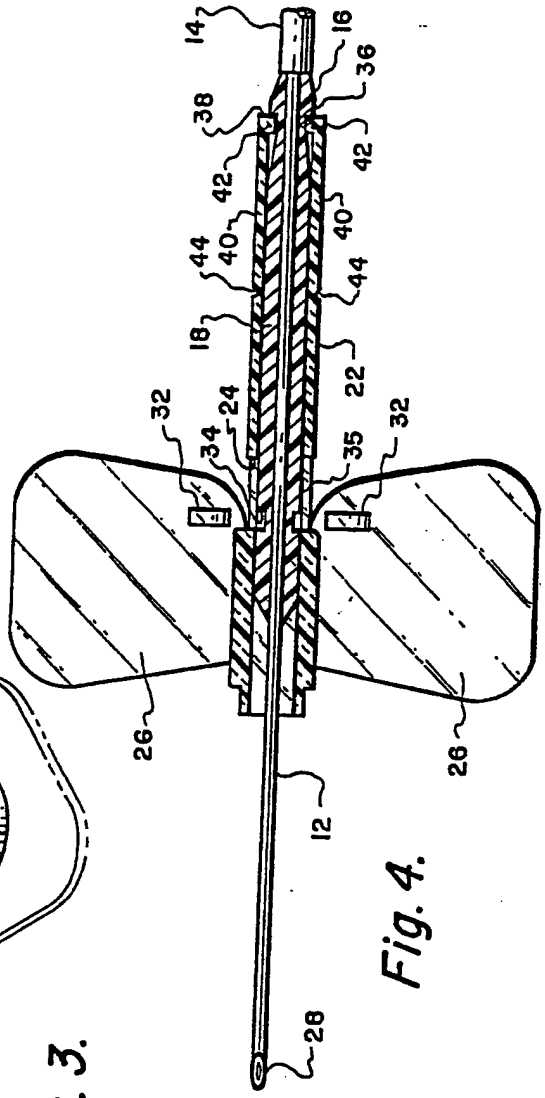

14
16
36
38
42
42
40
40
44
44
18
22
32
24
34
35
32
26
26
26
12
28

Fig. 4.

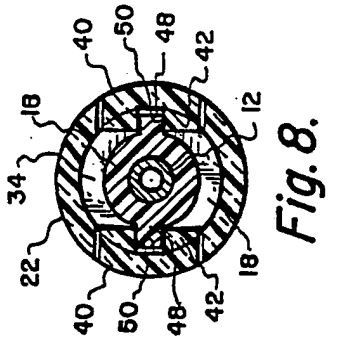


Fig. 8.

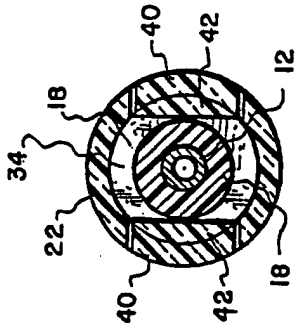


Fig. 7.

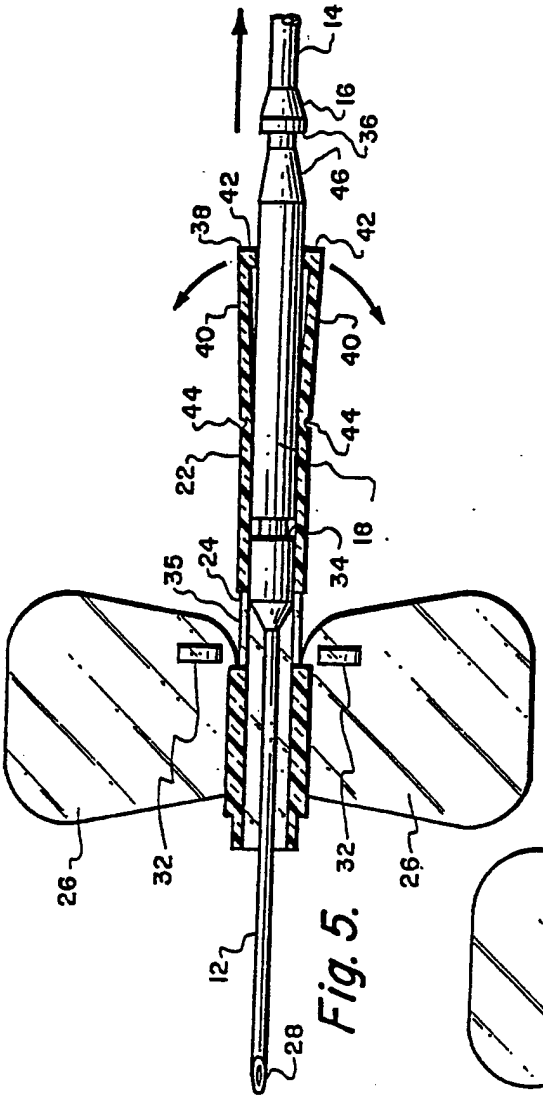


Fig. 5.

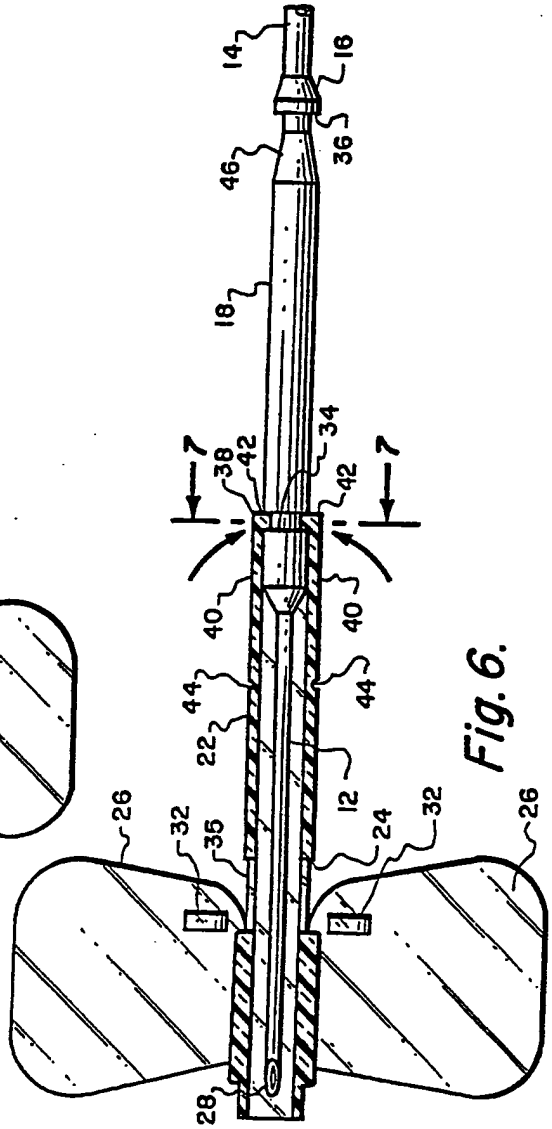


Fig. 6.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/00328

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61M 5/32
US CL: 604/177

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	604/171,177,198,110,174,180,162,164,165,263 128/919

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 4,676,783 (Jagger et al) 30 June 1987. See abstract and Figures 1-3.	1-4,6-12 & 14-16
X	US, A, 4,969,876 (Patterson) 13 November 1990. See Figures 1-4.	1-5,8-13 & 16
E,A	US, A, 5,085,639 (Ryan) 04 February 1992. See abstract.	1
A,P	US, A, 5,019,049 (Haining) 28 May 1991.	
A	US, A, 4,941,881 (Masters et al) 17 July 1990.	
A	US, A, 4,850,961 (Wanderer et al) 25 July 1989.	
A	US, A, 4,781,692 (Jagger et al) 01 November 1988.	
A	US, A, 4,194,504 (Harms et al) 25 March 1980.	
A	US, A, 4,192,304 (Millet) 11 March 1980.	

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
22 April 1992	29 MAY 1992

International Searching Authority	Signature of Authorized Officer
ISA/US	Mark O. Polutta

Form PCT/ISA/210 (second sheet) (Rev. 11-87)